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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,626	05/14/2001	Jerry L. Courson	N1430-001	7260

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WASHINGTON, DC 20005

EXAMINER
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IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/853,626

Applicant(s)  
Jerry Courson

Examiner  
Medina Ibrahim

Art Unit  
1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, and 34-46 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 9, 11, and 38-45 is/are allowed.
- 6) ☒ Claim(s) 8, 34-37, and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' response filed 3/03/03 in reply to the Office action mailed 09/10/02 and amendment B have been entered. Claims 10 and 12-33 have been cancelled. New claims 34-46 have been added. Therefore, claims 1-9, 11 and 34-46 are pending and are under examination.

All previous rejections and objections not stated below have been withdrawn.

### ***New Matter***

Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a hybrid corn seed wherein "fifty percent of its genetic material originates from the pollen of claim 3 " or "from the ovule of claim 4". However, the recitation "fifty percent of its genetic material" has no basis in the specification or in the claims as originally filed. Therefore, the phrase "fifty percent of its genetic material" is considered to be a new matter. Applicant is required to delete the new matter since it has no basis in the specification or in the claims as originally filed.

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***Claim Rejections - 35 USC § 112***

1. Claim 8 remains rejected and new claims 34-37 and 46 are rejected under 35 U.S.C. 112, **second** paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite because "protoplasts" lack antecedent basis in claim 7 which recites "tissue regenerable cells", as stated in the last Office action. Also, it is unclear how protoplasts can be isolated from protoplast, and neither protoplasts and nor calli are plant tissues. Are the "the cells or the protoplasts of said cells" intended to be the same as "the regenerable cells"? It is also unclear how the "derived" cells differ from the isolated cells.

In claims 34 and 35, what is encompassed by a "genetic material" is unclear. The specification fails to describe the phrase, and hence, the metes and bounds of the claim is unclear.

Claims 36 and 46 are indefinite in the recitation of "corn endosperm with improved nutritional quality" and "corn endosperm quality", respectively. The specification fails to describe what constitutes an "improved nutritional" or "endosperm quality", and hence, the metes and bounds of the claims are unclear. Dependent claim 37 is included in the rejection.

Claim 46 is indefinite in the recitation of "single gene conversion" because the usage of the term in Applicant's invention is inconsistent with usual meaning of the

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term, as stated in the last Office action, for cancelled claim 33. It is suggested that the phrase be replaced with ---transgene---. Further, claim 46 does not further limit or is improperly dependent on claim because the plant of claim 2 lacks a single gene conversion.

***Claim Rejections - 35 USC § 112, Enablement***

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 10/03/02, for cancelled claim 33. Applicant has not responded to the rejection in the response filed 03/03/03, and therefore, the rejection is maintained.

***Written Description***

Claims 34-37 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 10/03/02, for cancelled claims 12-16. Applicant has not responded to the rejection in the response filed 03/03/03, and therefore, the rejection is maintained.

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The claims are drawn to a hybrid corn seed wherein fifty percent of its genetic material is from the plant of the inbred line KW4636, a method for producing a transgenic corn plant by transforming the plant with a transgene that confers corn endosperm with improved nutritional quality, a plant produced by said method and corn plant of the inbred KW4636 further comprising a single gene conversion that confers corn endosperm quality.

The claimed invention does not meet the written description requirement for the following reasons: Even if fifty percent of the genetic material of the claimed seed is from KW4636, the other fifty percent of the genetic material is not described. Hence, the phenotypic characteristics of the seed and/or the plant produced from the seed are not described. Since each parent line contributes a set of alleles and these two sets of alleles interact in a variety of ways (influenced by the environment) to determine the phenotype of the progeny, one cannot predict how the genes of the known parent KW4636 will affect the phenotype of the F1 hybrid. It is not known how the known ( fifty percent) genotype would react with the environment or with other genes in the genome. The specification, page 3, lines 3-9, discusses the complexity of inheritance and states “ (t)he inbred lines which are developed are unpredictable. This unpredictability is because the breeder’s selection occurs in unique environments, with no control at the DNA level (using conventional breeding procedures)..... A breeder of ordinary skill in the art cannot predict the final resulting lines he develops.” Therefore, it is likely that

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F1 hybrids produced from each cross with KW4636 may be genetically distinct. A substantial variation in phenotypic and/or genotypic characteristics are expected among F1 hybrids. Therefore, the description of the genotype of a first parent by deposit, along with a description of the phenotypic characteristics of said first parent is insufficient to describe the claimed hybrid seed produced by crossing said first parent with any and all second parents which are not described. The rejection is maintained.

Regarding claims 36-37 and 46, Applicant has not described the broad class of transgenes that confer any and all types of improved endosperm nutritional quality, and therefore, one of skill in the art would not know that Applicant was in possession of a corn plant with improved nutritional quality at the time of filing. Consequently, the written description requirement is not satisfied.

***Remarks***

Claims 1-7, 9-11 and 38-45 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

May 28, 2003

mai



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